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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,065	09/13/2005	Heinz Von Der Kammer	37998-237382	5124

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VENABLE LLP
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/520,065	Applicant(s) VON DER KAMMER ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-16 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 17-19, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group XI, claims 9, 17-19, 24 and 25, in the reply filed on March 30, 2007 is acknowledged.

Claims 1-8, 10-16 and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 30, 2007.

Claims 9, 17-19, 24 and 25 are under examination in the instant office action.

Specification

2. The text of the instant specification, including drawings is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO: X, wherein "X" is the sequence number. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 9, 17-19, 24 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a

specific biological role for this protein or the significance of binding this protein to a specific physiological function or a clinical condition.

The instant claims are drawn to an assay for testing a compound for inhibition of binding between a ligand and TB2 protein. The instant specification discloses that “[h]uman TB2 is a putative membrane protein, [...] a member of an evolutionary conserved family of proteins including a mouse ortholog with 92% identity at the amino acid level [...]. The function of human TB2 is largely unknown” (p. 4 of the specification). It is further disclosed that TB2 is broadly expressed in different tissues and organs and that “it is reasonable to assume that TB2, as an integral membrane protein, participates in cellular membrane traffic involving the Golgi apparatus” (p. 4). The instant specification teaches finding of differential TB2 “gene expression on the transcriptional level in the temporal cortex region relative to the frontal lobe region, and in the hippocampal region relative to the frontal lobe region, respectively, of brain samples taken from AD patients. No such dysregulation is observed in samples derived from age-matched, healthy controls” (p. 5, see also pp. 10, 22, 23 and Figure 1).

Thus, the specification discloses finding of differential expression of TB2 in brain tissue of patients with AD but discloses no utilities based on detection of binding between a ligand and the TB2 protein, as currently claimed. In the absence of knowledge of the biological significance of this specific TB2 protein and its natural ligand, there appears to be no immediately obvious patentable use for an assay that measures inhibition of binding between a ligand and TB2 protein. According to the specification of the instant application the claimed “assay methods may be useful in the identification of novel compounds” for treatment of neurodegenerative diseases, such as Alzheimer’s disease, p. 20 and claims 24-25. However, there is no evidence of record to

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show that process of binding between a ligand and TB2 protein is associated with any disease or disorder, including Alzheimer's disease. Because the instant specification does not teach a biological significance of the binding between a ligand and TB2 protein, which supports a practical utility, one would not reasonably believe that the administration of a compound identified by the claimed assay would prevent, treat or ameliorate a condition or disease, like a neurodegenerative disease, as implied by the specification. As such, to employ an assay for testing a compound, as currently claimed, would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

Since the instant specification does not disclose a credible "real world" use for the assay for testing a compound for inhibition of binding between a ligand and TB2 protein in their

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currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9, 17-19, 24 and 25 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 9, 17-19, 24 and 25 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9, 17 and 24 recite fragments, derivatives or variants of a translation product of the gene encoding for TB2 polypeptides. Claims 18, 19 and 25 are dependent claims. The claims do not require that the polypeptides possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence similarity. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph,

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it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 1. The claims encompass proteins, which are fragments, derivatives or variants of a translation product of the gene encoding for TB2 to polypeptides. Thus, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the recited polypeptides to share some degree of structural similarity to the isolated protein of SEQ ID NO: 1. The specification only describes a protein having the amino acid sequence of SEQ ID NO: 1 and fails to teach or describe any other protein which lacks the amino acid sequence of SEQ ID NO: 1 and has any relevance to TB2.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of being a fragment, or derivative or a variant of the disclosed molecule. There is not even identification of any particular portion of the structure that must be conserved. The specification does not provide a complete structure of those polypeptides which are fragments, derivatives or variants of a translation product of the gene encoding for TB2 polypeptides and fails to provide a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claimed assay does not meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9, 17-19, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 9 and 17 are vague and indefinite in so far as they employ the term "TB2" as a limitation. This term appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "gene coding for TB2". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "TB2", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

11. Claims 9, 17-19 and 24 are vague and indefinite for recitation of "a ligand". It is not obvious as what ligand (any ligand, specific or non-specific, a naturally occurring or an artificial ligand for TB2 or all of the above) is intended by the claims. Clarification is required.

12. Claim 9 is further indefinite as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step that clearly connects measurement of amounts of detectable label associated with TB2 translation product (step v) and determination of inhibition of binding of a ligand (step vi). Further, since step (vi) requires determination of the degree of inhibition, the apparent comparison step also appears to be omitted.

13. Claim 19 recites limitation "the detectable label is fluorescence". Clarification of the limitation is required because the term "fluorescence" usually defines an optical phenomenon and, as "an event", it cannot be "a label".

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14. Claim 24 recites the limitation "the method" in claim 9. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 25 is indefinite for being dependent from indefinite claim.

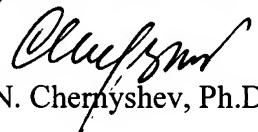
Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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Primary Examiner
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April 24, 2007